

JAN 22 2001

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR Part 807.92.

The assigned 510(k) number is: 1K003708

1. Date of summary: November 30, 2000
2. Submitted by: Advantage Diagnostics Corporation
1201 Douglas Ave.
Redwood City, CA 94063
TEL 650-569-3852
FAX 650-569-3856
3. Device Name: Advantage THC/COC Test
4. Device Classification: CFR 21 862.3870 and 862.3250, Class II, Panel 91 Toxicology
5. Device description: The Advantage THC/COC Test is an immunochromatographic based one step *in vitro* test.
6. Intended Use: The Advantage THC/COC Test is a qualitative, one step immunochromatographic competitive assay used to screen human urine for the presence of the cannabinoids at a cut off concentration of 50 ng/mL and cocaine and its metabolite, benzoylecgonine at a cut off of 300ng/mL. The test is qualitative and provides only a preliminary analytical result, which must be confirmed by an alternate methodology preferably, GC/MS.
7. Substantial Equivalence: The Advantage THC Test was found substantially equivalent to the Emit II Cannabinoid 100 ng/mL Assay and the Emit Cocaine 300ng/mL. Both products are immunoassays and use specific antibodies to detect various cannabinoid and cocaine compounds. Both assays are preliminary screens for human urine and require confirmation with alternate methods such as GC/MS. The sensitivity of the tests are similar, the Emit II detects cannabinoid compounds at a cut off of 100ng/mL and the Advantage THC Test at a cut off of 50ng/mL. Both tests detect Cocaine at 300ng/mL. The tests demonstrated 98% correlation when 151 clinical specimens (50 negative and 101 positive) were compared. The tests are similar in sensitivity, specificity, accuracy and precision. The Advantage THC/COC cut offs were validated by comparing results to GC/MS, a correlation of 97% was found.

Conclusion:

The Emit II Cannabinoid 100ng Assay and Cocaine 300ng assay and the Advantage THC/COC Test are substantially equivalent in performance characteristics. The correlation of the two tests was 98%. The correlation between the Advantage THC/COC and GC/MS was 97%.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 22 2001

Ms. Janis Freestone
Director, Regulatory Affairs
Advantage Diagnostics Corporation
1201 Douglas Avenue
Redwood City, California 94063

Re: K003708
Trade Name: Advantage THC/Cocaine Test
Regulatory Class: II
Product Code: DIO, LDJ
Dated: November 30, 2000
Received: December 1, 2000

Dear Ms. Freestone:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.

Director

Division of Clinical Laboratory Devices

Office of Device Evaluation

Center for Devices and Radiological Health

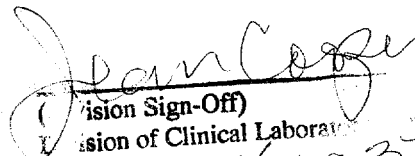
Enclosure

510k Number: K 003708

Device Name:
Advantage THC/Cocaine Test

Indications for Use:

The Advantage THC/Cocaine Test is a qualitative, one step, immunochromatographic competitive assay used to screen human urine for the presence of cannabinoid at a cut off concentration of 50ng/mL and benzoylecgonine at a cut off of 300ng/mL. The test is qualitative and provides only a preliminary analytical result, which must be confirmed by an alternate methodology preferably, GC/MS.


() Vision Sign-Off
Division of Clinical Laboratory
510(k) Number K003708

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over the counter use _____